

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/024,858	LEONARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02 February 2006.
2. ☒ The allowed claim(s) is/are 25 and 26.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 08/817,911.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 2/2/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 3/13/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*Humera N. Sheikh*  
**PATENT EXAMINER**  
 TC-1600

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Request for Continued Examination (RCE) under 37 CFR §1.114 filed 02/02/06 and the Information Disclosure Statement (IDS) filed 02/02/06 is acknowledged.

Claims 25 and 26 are pending in this action. Claims 25 and 26 are allowed.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 02/02/06 has been entered.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 02/02/06 was filed after the mailing date of the Notice of Allowance on 01/13/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Wayne J. Dustman on 03/13/06.

The application has been amended as follows:

In the Specification:

On page 1, in the Continuation Data after the title, after the term "September 9, 1999," the terms "**now U.S. Patent No. 6,548,084**" has been **added**.

On page 1, in the Continuation Data, after the term "Serial No. 08/817,911," the term "**filed August 26, 1997, now abandoned**" has been **added**.

In the Claims:

In claim 26, line 2, after the term "from", the phrase "**the group consisting of**" has been added.

*Allowable Subject Matter*

Claims 25 and 26 are allowed.

The following is an examiner's statement of reasons for allowance:

The instant invention is drawn to a composition that reduces the incidence of nausea and vomiting associated with the administration of paroxetine, comprising paroxetine, or a pharmaceutically acceptable salt thereof, in a controlled and delayed release swallow pharmaceutical formulation that, upon administration, releases the paroxetine predominantly in the small intestine.

The primary reason for allowance is that the prior art (Johnson WO 92/09281) does not disclose nor fairly suggest a composition comprising paroxetine in both a controlled and delayed release formulation and does not teach a method of treating one or more diseases states as claimed in instant claim 26. Rather, the prior art merely indicates that delayed *or* controlled formulations were known, however, the prior art itself, does not teach or suggest a formulation comprising a controlled and delayed release formulation. Applicants specification contains and defines the terms 'controlled release' and 'delayed release' formulations. The instant specification also contains multiple examples demonstrating paroxetine compositions in controlled and delayed release formulations. The controlled and delayed release combination of paroxetine as instantly claimed provides an unexpected reduction in the side effects associated with the administration of paroxetine using, for example, swallow tablets. Hence beneficial and improved results are obtained through the use of a formulation of paroxetine having both controlled and delayed release, as instantly claimed.

In the in-person interview between Applicant's representative, Wayne Dustman and Charlie Van Horn, Supervisory Examiner T. K. Page and myself, Examiner Sheikh on June 02, 2004, Applicants had fully demonstrated that the prior art fails to provide any disclosure or teaching or suggestion of a paroxetine composition provided in both a controlled and delayed release formulation that release the paroxetine predominantly in the small intestine. Additionally, Applicants had demonstrated that the instant invention provides for superior results in that the incidence of nausea and vomiting associated with administering paroxetine were greatly reduced using the controlled and delayed release swallow paroxetine formulation of the present invention.

Hence, in view of the improvements demonstrated by the instant invention and the lack of teachings (controlled & delayed release of paroxetine) by the prior art, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

March 13, 2006

*Humera N. Sheikh*  
*TC-1600*

*hns*